Application No. 10/583,157

January 21, 2009

Reply to Office Action of August 19, 2008

## **AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions and listings of claims in the application:

## **Listing of Claims:**

- 1. (original) A pharmaceutical composition which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine (NDSB).
- 2. (original) The pharmaceutical composition according to claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of a therapeutically effective synthetic or natural organic molecule and a therapeutically effective protein.
- 3. (original) The pharmaceutical composition according to claim 2, wherein the therapeutically effective protein is selected from the group consisting of granulocyte-colony stimulating factor, interferons, interleukins, granulocyte-macrophage colony-stimulating factor, macrophage colony-stimulating factor, epidermal growth factor, erythropoietin, follicle-stimulating hormone, human serum albumin, deoxyribonuclease, fibroblast calcitonin, hematoprotein; plasminogenic activators and their precursors, cytokines; TNF family of ligands, soluble receptors, growth hormones, lipoproteins; alpha-1-antitrypsin; insulin, proinsulin, subunit A of insulin, subunit B of insulin; glucagons; blood coagulation factors, bombasine; thrombin; enkephalinase; macrophage inflammatory protein (MIP-1-alpha); relaxin A subunit, relaxin B subunit, prorelaxin; inhibin; activin; vascular endothelial growth factor; hormone receptors or growth factor receptors; integrins; protein A, protein D; rheumatoid factors; bone-derived neurotrophic factor, neurotropin-3, -4, -5, or 6; nerve growth factor, platelet-derived growth factor, fibroblast growth factor, transformed growth factor, insulin-like growth factor, thrombopoietin, bone morphogenetic protein and superoxide dismutase.
- 4. (original) The pharmaceutical composition according to claim 3, wherein the therapeutically effective protein is G-CSF.
- 5. (previously presented) The pharmaceutical composition according to claim 1, wherein the NDSB is quaternary ammonium salt of Formula 1, wherein R1, R2 and R3 can be the same

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and/or different and are selected from the group consisting of methyl, ethyl, propyl, butyl, pentyl, hexyl or their derivatives, and R4 is (CH<sub>2</sub>)<sub>n</sub>, wherein n is between 1 and 6.

- 6. (original) The pharmaceutical composition according to claim 5, wherein the NDSB is selected from the group consisting of dimethylethyl-(3-sulphopropyl)-ammonium salt, 3-(1-pyridino)-1-propanesulfonate, dimethylbenzylammonium propanesulfonate, dimethyl-t-butyl-(3-sulphopropyl)ammonium salt, 3-(1-methylpiperidine)-1-propanesulfonate and dimethyl-(2-hydroxyethyl)-(sulphopropyl)-ammonium salt.
- 7. (original) The pharmaceutical composition according to claim 6, wherein the NDSB is dimethyl-t-butyl-(3-sulphopropyl)ammonium salt.
- 8. (previously presented) The pharmaceutical composition according to claim 1 wherein said composition optionally further comprises a polyol.
- 9. (original) The pharmaceutical composition according to claim 8, wherein the polyol is selected from the group consisting of sorbitol, glycerol, inositol, trehalose and mannitol.
- 10. (previously presented) The pharmaceutical composition according claim 1, wherein said composition optionally further comprises one or more pharmaceutically acceptable excipients.
- 11. (original) The pharmaceutical composition according to claim 10, wherein a pharmaceutically acceptable excipient is selected from the group consisting of EDTA and DMSO.
- 12. (currently amended) A process for preparation of a pharmaceutical composition, wherein [[a]]the pharmaceutical composition of claim 1 is prepared by mixing a NDSB with therapeutically effective amount of an active pharmaceutical ingredient.
- 13. (cancelled)

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- 14. (withdrawn) A method of using a NDSB as a stabiliser in a pharmaceutical composition.
- 15. (withdrawn) A method of using a NDSB as a buffering agent in a pharmaceutical composition.
- 16. (withdrawn) A method of using a NDSB as a pH adjusting agent in a pharmaceutical composition.